

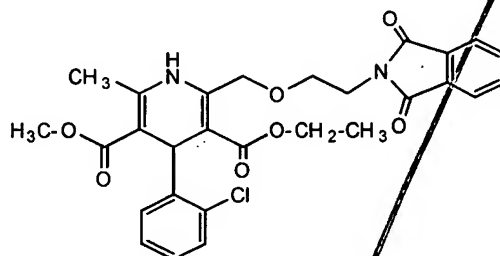
Sub 01

We Claim:

1. A pharmaceutical tablet composition comprising an effective amount of amlodipine free base and at least one pharmaceutically acceptable excipient; wherein said tablet exhibits low punch residue.
2. The composition according to claim 1, wherein said tablet leaves an average residue on the tablet punch of  $0.7 \mu\text{g}\cdot\text{cm}^{-2}$  per tablet or less.
3. The composition according to claim 1, wherein said excipient is a calcium phosphate.
4. The composition according to claim 1, wherein said excipient is microcrystalline cellulose.
5. The composition according to claim 3, which further comprises microcrystalline cellulose.
6. The composition according to claim 5, wherein said calcium phosphate is anhydrous calcium hydrogen phosphate.
7. The composition according to claim 1, wherein said amlodipine free base is crystalline form II amlodipine free base.
8. The composition according to claim 1, wherein said amlodipine free base is amorphous amlodipine free base.
9. The composition according to claim 1, wherein said amlodipine is a mixture of crystalline amlodipine free base form I and form II.
10. The composition according to claim 1, wherein said tablet contains 1 to 100 mg of said amlodipine free base.
11. Crystalline amlodipine free base of form II.
12. A method of treating or preventing hypertension, angina, or congestive heart failure, which comprises administering an effective amount of amlodipine free base to a patient in need thereof.
13. A process which comprises:  
deprotecting an ~~am~~-protected amlodipine with a deprotecting agent to form amlodipine free base;

precipitating said amlodipine free base from a solution; and  
isolating said precipitated amlodipine free base in solid state form.

14. The process according to claim 13, wherein said solution is formed by said deprotecting step.
15. The process according to claim 14, wherein said solution contains water.
16. The process according to claim 13, wherein said N-protected amlodipine is phthalodipine of formula (2a):



(2a).

17. The process according to claim 16, wherein said deprotecting agent is aqueous methylamine.
18. The process according to claim 13, wherein said deprotecting step occurs in an aqueous solution or slurry.
19. The process according to claim 18, which further comprises extracting said amlodipine free base in a water immiscible solvent to form said solution.
20. The process according to claim 19, wherein said water immiscible solvent is toluene.
21. The process according to claim 13, wherein said precipitation is a crystallization step.
22. The process according to claim 21, wherein said crystallization comprises cooling said solution.
23. The process according to claim 22, wherein said crystallization additionally comprises evaporating a portion of the solvent from said solution.
24. The process according to claim 21, wherein said crystallization comprises adding a contra-solvent to said solution.

25. The process according to claim 22, wherein said crystallization begins at a temperature above 5°C.
26. The process according to claim 22, wherein said crystallization begins at a temperature of 5°C or less and said solution is based on a non-aqueous solvent.
27. The process according to claim 13, wherein said isolated amlodipine free base is crystalline form I amlodipine free base.
28. The process according to claim 13, wherein said isolated amlodipine free base is crystalline form II amlodipine free base.
29. The process according to claim 13, which further comprises dissolving said isolated amlodipine free base in a non-aqueous purification solvent and crystallizing said dissolved free base from said purification solvent to form purified crystalline amlodipine free base.
30. A process for purifying amlodipine free base, which comprises: crystallizing amlodipine free base from a non-aqueous solvent.
31. The process according to claim 30, wherein said crystallization produces amlodipine free base crystals having an average particle size of 150 to 350 microns.
32. A population of particulate amlodipine free base having an average particle size of at least 100 microns.
33. The population according to claim 32, wherein said particles are crystals.
33. The population according to claim 33, wherein said average particle size is 150 to 350 microns.

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